UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

23552

7590

12/02/2009

MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903 EXAMINER

CAMPBELL, VICTORIA P

ART UNIT PAPER NUMBER

3763

DATE MAILED: 12/02/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,736	11/10/2003	James Marrs	14485.0155US01	4988

TITLE OF INVENTION: SUBCUTANEOUS INFUSION DEVICE AND METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	03/02/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

appropriate. All further indicated unless correcte maintenance fee notifical	correspondence includired below or directed oth tions.	ng the Patent, advance on herwise in Block 1, by (a	rders and notification of a) specifying a new corre	maintenance fees waspondence address;	ill be and/or	mailed to the current r (b) indicating a sepa	correspondence address as trate "FEE ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)				Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.			
23552	7590 12/02	/2009	nav			e of Mailing or Trans	mission
MERCHANT (P.O. BOX 2903 MINNEAPOLIS	& GOULD PC 5, MN 55402-0903		I h Sta ado trai	ereby certify that th tes Postal Service w lressed to the Mail asmitted to the USP	in Fee(tith suf Stop TO (57	s) Transmittal is being ficient postage for first ISSUE FEE address [1] 273-2885, on the d	Inission g deposited with the United st class mail in an envelope above, or being facsimile ate indicated below.
							(Depositor's name)
							(Signature)
							(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	₹	ATTO	RNEY DOCKET NO.	CONFIRMATION NO.
10/705,736	11/10/2003	•	James Marrs		1-	4485.0155US01	4988
APPLN, TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUI	E FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	3122	\$1810	03/02/2010
			· 1	٦		\$1010	03/02/2010
EXAMINER		ART UNIT	CLASS-SUBCLASS	J			
CAMPBELL, 1. Change of corresponde		3763	2. For printing on the	notant front nago lic			
CFR 1.363). Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.			or agents OR, alternat (2) the name of a sing registered attorney or	ne of a single firm (having as a member a attorney or agent) and the names of up to d natent attorneys or agents. If no name is			
PLEASE NOTE: Unl	ess an assignee is ident h in 37 CFR 3.11. Comp	ified below, no assignee	THE PATENT (print or ty data will appear on the p T a substitute for filing an (B) RESIDENCE: (CIT	patent. If an assign assignment.			ocument has been filed for
Please check the appropri	iate assignee category or	categories (will not be pr	rinted on the patent):	Individual 🖵 Co	orporati	ion or other private gro	oup entity 🗖 Government
'	are submitted: To small entity discount p # of Copies	permitted)	o. Payment of Fee(s): (Ple A check is enclosed. Payment by credit ca The Director is hereb overpayment, to Dep	rd. Form PTO-2038 v authorized to char	is atta	ached. required fee(s), any de	
5. Change in Entity Stat	tus (from status indicated s SMALL ENTITY statu		☐ b. Applicant is no lor	agar claiming SMAI	I EN	TITV status See 37 C	EP 1 27(a)(2)
• •				-			ne assignee or other party in
Authorized Signature				Date			
Typed or printed name				_			
This collection of inform an application. Confident submitting the completed his form and/or suggesti Box 1450, Alexandria, V Alexandria. Virginia 223	tiality is governed by 35 I application form to the ons for reducing this but irginia 22313-1450. DC	FR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary den, should be sent to th ONOT SEND FEES OR (on is required to obtain or 1.14. This collection is es depending upon the indi e Chief Information Offic COMPLETED FORMS T	retain a benefit by t stimated to take 12 r vidual case. Any co er, U.S. Patent and O THIS ADDRESS	he publ ninutes mment Traden S. SENI	lic which is to file (and s to complete, including ts on the amount of timerk Office, U.S. Depo D TO: Commissioner	by the USPTO to process) g gathering, preparing, and me you require to complete artment of Commerce, P.O. for Patents, P.O. Box 1450,

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450

P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/705,736 11/10/2003		James Marrs	14485.0155US01	4988	
23552 75	23552 7590 12/02/2009		EXAMINER		
MERCHANT &	GOULD PC	CAMPBELL, VICTORIA P			
P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			ART UNIT	PAPER NUMBER	
			3763 DATE MAILED: 12/02/2009		

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 713 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 713 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)
Notice of Allowability	10/705,736 Examiner	MARRS ET AL. Art Unit
Notice of Allowalinty	Examiner	Art onit
	VICTORIA P. CAMPBELL	3763
The MAILING DATE of this communication appeal all claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R	(OR REMAINS) CLOSED in the or other appropriate communication. This application is sub-	is application. If not included cation will be mailed in due course. THIS
1. This communication is responsive to <u>10/27/09</u> .		
2. ☑ The allowed claim(s) is/are <u>1 and 5-12</u> .		
 3. Acknowledgment is made of a claim for foreign priority ur a) All b) Some* c) None of the: 1. Certified copies of the priority documents have 2. Certified copies of the priority documents have 	e been received.	
3. ☐ Copies of the certified copies of the priority do	• •	
International Bureau (PCT Rule 17.2(a)).		and national otago approation from the
* Certified copies not received:		
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submin INFORMAL PATENT APPLICATION (PTO-152) which give	IENT of this application. itted. Note the attached EXAM	INER'S AMENDMENT or NOTICE OF
5. CORRECTED DRAWINGS (as "replacement sheets") mus	· , -	solution to denote it.
(a) ☐ including changes required by the Notice of Draftspers		PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date		1 10 340, attached
(b) ☐ including changes required by the attached Examiner's Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1	s Amendment / Comment or in	
each sheet. Replacement sheet(s) should be labeled as such in t		
 DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT 		
Attachment(s) 1. ☐ Notice of References Cited (PTO-892)	5 Notice of Infor	mal Datant Application
 Induce of References Cited (PTO-692) Induce of Draftperson's Patent Drawing Review (PTO-948) 	6. ☐ Interview Sum	mal Patent Application
 Information Disclosure Statements (PTO/SB/08), 	Paper No./Ma	nial y (F10-413), nil Date nendment/Comment
Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit		atement of Reasons for Allowance
of Biological Material	9.	

Application/Control Number: 10/705,736 Page 2

Art Unit: 3763

DETAILED ACTION

Response to Arguments

1. In response to applicant's argument regarding the previous objection to the specification, the examiner notes the specification amendment filed January 9, 2008 is sufficient and hereby withdraws the previous objection.

Allowable Subject Matter

- 2. Claims 1 and 5-12 as amended in the After Final response filed October 27, 2009 are allowed over the prior art of record.
- 3. The following is an examiner's statement of reasons for allowance: The claims in this application have been allowed because the prior art of record fails to teach or disclose, either singly or in combination, the claimed site for a subcutaneous infusion device, comprising a base, a cannula configured to be introduced subcutaneously using a needle, and a single unitary diaphragm is coupled to the base, the diaphragm including a closed end, and open end, and a sidewall, and defining an internal reservoir in fluid communication with the cannula; wherein the single diaphragm is pierceable through the upper end and through the sidewall, and the diaphragm is positioned in a cavity of a member positioned about the central aperture of the base and frictionally engages the interior wall of the member to retain the diaphragm in the cavity.
- 4. The closest prior art of record is Fischell (USPN 5,545,143). However, this reference does not disclose the invention as claimed or described above.

Application/Control Number: 10/705,736 Page 3

Art Unit: 3763

5. Regarding claims 1 and 9, the closest prior art of record fails to teach among all the limitations or render obvious a single diaphragm positioned in a cavity of a member and frictionally engaged with the walls of the cavity in order to retain it in the cavity.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/705,736 Page 4

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell Examiner, AU 3763

/Nicholas D Lucchesi/ Supervisory Patent Examiner, Art Unit 3763